



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

**DePaoli, Alex, et al.**

**Serial No.:** 10/623,189

**Filed:** July 18, 2003

**For: Use of Leptin for Treating  
Human Lipoatrophy and Method of  
Determining Predisposition to Said  
Treatment**

**Examiner:** O' Hara, Eileen B

**Group Art Unit:** 1646

**Docket No.:** 54113.8005.US02

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being deposited on April 12, 2006 with the United States Postal Service as first class mail in an envelope addressed to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
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Amy Shields

**RESPONSE TO RESTRICTION REQUIREMENT**

Mail Stop Amendment  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

The following is in response to the Restriction Requirement mailed January 12, 2006 for the above-identified application. A request for a two-month extension of time to respond to this communication is filed concurrently herewith, making this response timely.

Claims 1-32 are currently pending in the application. The Office Action divides these claims into allegedly distinct groups of inventions, Groups I-IV. Applicants hereby elect Group I, which includes claims 1-21, 23, 24 and 29-31, with traverse. Applicants expressly reserve their right under 35 U.S.C. § 121 to file a

divisional application directed to the nonelected subject matter during the pendency of this application, or an application claiming priority from this application.

Applicants respectfully traverse the restriction between Group I (claims 1-21, 23, 24 and 29-31) and Group II (claim 22). Claim 1 states that lipoatrophy is treated with "an effective dose of leptin..." and does not specify whether the leptin is in a nucleic acid form or amino acid form upon administration. The claims of the two groups are related by a genus-species relationship and a search of the genus (Group I) would necessarily encompass the search of the species (Group II). M.P.E.P. 803 states that where search and examination of the entire application can be carried out without a serious burden, the Examiner must examine the application on the merits even if it includes claims to independent or distinct inventions. As such, Applicants respectfully assert that the Examiner should combine Groups I and II and examine claims 1-24 and 29-31 together.

Applicants also respectfully traverse the restriction between Groups III (claims 25-28) and IV (claim 32). Group III is directed to methods of determining a predisposition of a lipoatrophic patient to respond to leptin treatment through determining the leptin level of the patient prior to the treatment and Group IV is directed to a kit for accomplishing such methods. Applicants submit that the claims of Group III and Group IV are related in such a way that examination of both would not unduly burden the Examiner.

Applicants respectfully request reconsideration of the restriction requirement between Groups I and II and between Groups III and IV.

With regard to Group I, the restriction requirement further states at page 4 that Applicant must elect a single "patentably distinct species of the claimed invention." Applicants hereby elect hyperglycemia. The restriction requirement further requires election of an additional treatment compound. Without comment on the patentable distinctiveness of the compounds in the Markush grouping, Applicants hereby elect metformin. Applicants request that, upon allowance of a generic claim, the remainder of the species be included as permitted under 37 C.F.R. §1.141.

Applicants believe that this addresses all of the issues set forth in the restriction requirement. If Applicant can do anything more to expedite this application, please contact the undersigned at (310) 788-3245.

Respectfully submitted,  
Perkins Coie LLP

Date: April 12, 2006



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